K070530

MEDICREA

SPECIAL 510(K) SUMMARY

OCT 18 2007

1. GENERAL INFORMATION

Trade Name	PASSmed Spinal System
Common Name	✓ Posterior pedicle screw system ✓ Sacral plate ✓ Hooks
Classification Name	✓ Pedicle screw spinal system ✓ Spinal interlaminal fixation orthosis
Class	Class II
Product Code	MNH / MNI / KWP
CFR section	888.3070 / 888.3050
Device panel	Orthopedic
Legally marketed predicate devices	Medicrea PASSMed Spinal System: K032094 Medtronic CD Horizon®: K014296 EBI® Array™ Spinal Fixation System: K042772
Reason for special 510(k)	Product range extension and additional components
Submitter	MEDICREA® Technologies Z.I. Chef de Baie 17000 La Rochelle, France
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 E-Mail: ortho.medix@sbcglobal.net

2. PREDICATE DEVICE DESCRIPTION

The PASSmed Spinal System consists of pedicle screws, hooks, sacral plates, clamps, rods, nuts, rod plates and crosslink members. It can be used for single or multiple level fixations. All components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 and titanium unalloyed (T40) that conforms to ASTM F67.

3. DESCRIPTION OF DEVICE MODIFICATION

The purpose of this submission is to include the following components in PASSmed Spinal System:

- Ø6mm rod in length 500mm for in-situ bending: same design as rods cleared in K032094. This rod is manufactured from unalloyed titanium that conforms to ASTM F67
- Connectors (dominoes) to connect a rod Ø6mm to another rod Ø6mm

4. INTENDED USE

The PASSmed which includes the subject components, is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

As a pedicle screw system PASSmed is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

It also includes hooks and a sacral plate indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

5. PERFORMANCE DATA

When applicable, the tests performed on the additional components according to ASTM F1717 or ASTM F1798, indicate that the products are as mechanically sound as other PASSmed devices commercially available

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MEDICREA Technologies
% Mr. J. D. Webb
1001 Oakwood Blvd.
Round Rock, TX 78641

OCT 18 2007

Re: K070530
Trade/Device Name: PASSmed Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP
Dated: September 16, 2007
Received: September 19, 2007

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MEDICREA

INDICATIONS FOR USE

510(k) Number (if known): K070530

Device Name: PASSmed Spinal System

PASSmed Spinal System

Indications for Use

The PASSmed is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070530